(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 757 571 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
10.03.2004 Bulletin 2004/11

(21) Application number: **95917075.4**

(22) Date of filing: **18.04.1995**

(51) Int Cl.[7]: **A61M 29/00**, A61F 2/06

(86) International application number:
PCT/US1995/004838

(87) International publication number:
WO 1995/029728 (09.11.1995 Gazette 1995/48)

(54) **ENDOPROSTHESES AND STENTS**

ENDOPROTHESEN UND STENTS

ENDOPROTHESES ET EXTENSEURS

(84) Designated Contracting States:
DE FR GB IE

(30) Priority: **28.04.1994 US 234473**

(43) Date of publication of application:
12.02.1997 Bulletin 1997/07

(60) Divisional application:
03104772.3

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WO-A-94/01056
US-A- 5 122 154

EP 0 757 571 B1

Printed by Jouve, 75001 PARIS (FR)

Description

[0001] The invention relates to placement of tubular endoprostheses or stents for body passages, particularly for opening, dilating and maintaining blood vessels and other biological ducts which are at risk of closure due to flaps, dissections, loose vessel debris, etc.

[0002] The general use of endoprostheses for such purposes is well known. In one technique a tubular endoprosthesis is mounted over an inflatable balloon of corresponding length, which is part of a disposable balloon catheter. The catheter is inserted into a vessel or duct and guided to the desired site. The balloon is then expanded to expand and permanently secure the endoprosthesis at the site. After this the balloon is deflated and the catheter is withdrawn to complete the placement sequence, and the balloon catheter is discarded. When the region of the blood vessel or duct requires placement over a length greater than the length of a standard prosthesis, often two of the prostheses are placed by their respective balloon catheters in end-to-end relationship with some overlap. This requires two separate placement sequences, requires the use of two disposable balloon catheters, and creates a number of problems both in placement and in use. Other techniques seeking to use long endoprostheses and stents have had drawbacks related to placement or use. In WO-A-94-01056 the anchoring ends of the endoprosthesis are self-expandable and a central portion is expandable in a single step by a balloon wall portion of the catheter.

[0003] US-A-5122134 discloses a medical device comprising a catheter having a radially expandable portion;

a tubular shaped, elongate endoprosthesis mounted on the catheter, the axial length of the radially expandable portion of the catheter being less than the axial length of the endoprosthesis;

the endoprosthesis is capable of radial expansion progressively in the axial direction, by means of the radially expandable portion of the catheter;

the radially expandable portion of the catheter is disposed within the portion of the endoprosthesis that is to be first expanded.

[0004] The present invention is characterised in that the endoprosthesis comprises a filament material extending throughout the length of the endoprosthesis, the filament material being interconnected at a multiplicity of points along the length.

[0005] Such a device for implanting an endoprosthesis within the lumen of a body passageway allows a tubular shaped, elongate endoprosthesis having a small first diameter to be delivered into a selected body passageway. The endoprosthesis is capable of being progressively permanently deformed to an expanded diameter upon application of radial, outwardly acting force applied to the interior wall of the endoprosthesis by the inflatable, radially expandable portion of the catheter. With the catheter positioned within the endoprosthesis so that its expandable portion registers with a first portion of the endoprosthesis, inflating the inflatable portion of the catheter causes the deformation of the first portion of the endoprosthesis to a second, expanded diameter. The inflatable portion of the catheter can then be deflated and axially shifted within the endoprosthesis while the inflatable portion is in the deflated state until the inflatable portion registers with an unexpanded portion of the endoprosthesis. The inflation of the inflatable portion of the catheter can then be repeated at least one additional time until the endoprosthesis is expanded throughout the desired length, and the endoprosthesis is permanently placed in supporting relationship within the lumen of the body passageway. The catheter is then withdrawn.

[0006] Preferred embodiments of this aspect of the invention have one or more of the features found in claims 2 to 16.

[0007] The first portion of the endoprosthesis may have an initial unexpanded diameter smaller than the unexpanded diameter of remaining portions of the endoprosthesis such that the initial diameter of the first portion secures the endoprosthesis upon the expandable portion of the catheter for insertion, and the diameter of the remaining portions of the endoprosthesis enables the catheter, after expansion of the first portion of the endoprosthesis, to be moved axially within the endoprosthesis when the inflatable portion is in at least a partially deflated state.

[0008] Alternatively, the endoprosthesis in unexpanded state is of uniform size and is detachably secured over the inflatable portion prior to insertion into the body.

[0009] The endoprosthesis may be secured by partially inflating the inflatable portion sufficiently to secure the endoprosthesis to the catheter prior to insertion into the body.

[0010] The long endoprosthesis is preferably of knitted construction enabling it to conform to tortuosities of the duct.

[0011] It has been realized that disadvantages of prior techniques can be overcome by employing a longer than usual endoprosthesis and an axially movable balloon intentionally substantially shorter than the endoprosthesis. The same balloon is then employed to inflate different sections of the endoprosthesis, by axially shifting the balloon within the endoprosthesis between inflations.

[0012] Prior art expandable tubular endoprostheses, and in particular vascular stents, have often ranged from 2 to 14 mm diameter and generally have been limited to about 8 cm in length because of limits on practical balloon length. As the length of the balloon increases, uniform balloon expansion is difficult to achieve, and if the balloon is too long it will cause the endoprosthesis to be expanded in a non-uniform, undesirable way.

[0013] One of the advantages of the technique provided by the device of the invention is that it can ensure uniform expansion throughout the length of a long en-

doprosthesis. Another advantage is avoiding the time-consuming step of overlapping one endoprosthesis over the next. Avoidance of overlap furthermore avoids rigidity and reduced flexibility of the endoprosthesis at the region of the overlap, and therefore avoids differences in compliance created along the length of the vessel. Differences in compliance have been shown by vascular surgeons to create areas where stenosis becomes more aggressive. The invention can also avoid a . decrease in the diameter of the lumen at the overlap which may present blood flow abnormalities and lead to increased likelihood of thrombosis. The invention also eliminates the need, after each section of endoprosthesis is positioned, to remove the catheter from the patient's body and insert a new catheter and endoprosthesis and thus can reduce the duration of the procedure and the patient's risk of infection.

[0014] In a device according to the invention, a balloon of standard length may be employed to place any length endoprosthesis. The surgeon simply inflates the balloon to dilate one section of the endoprosthesis, deflates the balloon, moves the balloon distally a distance slightly short of one balloon length, then reinflates the balloon, and repeats this procedure until the entire length of the endoprosthesis is expanded. Such a standard length balloon can be selected to be relatively short, which can facilitate placement of long endoprostheses to severely tortuous pathways. Placement in such tortuous pathways is particularly effective when the stent is of knitted construction.

[0015] Examples of devices according to the present invention will now be described with reference to the accompanying drawings, in which:-

Fig. 1 shows an unexpanded endoprosthesis mounted on the distal end of a dilation balloon.

Fig. 1a shows the long unexpanded endoprosthesis component of the device of Fig. 1 of length L_E

Fig. 1b shows the balloon catheter component of the device of Fig. 1 with a relatively short deflated dilation balloon of length L_B.

Fig. 1c shows the balloon catheter of Fig. 1b with the dilation balloon inflated.

Fig. 2 shows the endoprosthesis of Fig. 1 with the dilation balloon expanded at the distal end as a result of the first expansion stage during the insertion procedure.

Fig. 3 shows the endoprosthesis of Fig. 1 expanded for a distance of about two balloon lengths as a result of the second stage of expansion.

Fig. 4 is a rear view of a partially occluded small saphenous vein.

Fig. 5 is longitudinal diagrammatic cross sectional view of enlarged scale of the vein of Fig. 4 taken along line 5-5 with the unexpanded endoprosthesis in place, with the dilation balloon at the distal end of the treatment site.

Fig. 6 is a view similar to Fig. 5 with the dilation balloon expanded in the first stage of expansion.

Fig. 7 is a view similar to Fig. 5 with the endoprosthesis expanded about two balloon lengths as a result of the second stage expansion.

Fig. 8 shows the endoprosthesis fully expanded and the catheter withdrawn.

Fig. 9 shows an endoprosthesis with an initial unexpanded length L_I of smaller diameter than the unexpanded remaining length L_R.

Description of the Preferred Embodiment(s)

[0016] Referring to Figs. 1-3, in the preferred embodiment, the device 1 comprises catheter body 2 upon which a standard 4 cm length dilation balloon 3 is mounted, as shown in Fig. 1b. A 17 cm length, 14 mm diameter endoprosthesis 4 is disposed over the catheter with the endoprosthesis 4 registering with the distal end of the balloon. The length L_E of endoprosthesis 4 is substantially longer than the length L_B of dilation balloon 3, as shown in Figs. 1a and 1b. The endoprosthesis 4 is knitted from a biocompatible, corrosion resistant, negatively charged, highly radiopaque material (e.g., tantalum). The dilation balloon 3 is of a set inflated dimension and is formed of a non-compliant or inelastic material (e.g., polyethylene or polyethylene teraphalatate) which is folded into a small dimension, and inserted into the distal end of the stent where it is secured, as shown in Fig. 1. After placement, upon inflation, the dilation balloon 3 unfolds until it reaches a maximum dimension as shown by itself in Fig. 1c. During the first stage of inflation, the condition of Fig. 2 is achieved after deflation and proximal axial shifting of the catheter one balloon length to the left to position L. The stent is then expanded again to achieve the condition of Fig. 3. Thereafter successive deflating, axially shifting and reinflating after each inflation stage enables complete expansion of the stent.

[0017] Referring now to Fig. 4, the endoprosthesis 4 may be used in the longer veins and arteries of the body (e.g., the small saphenous vein 5 of the leg) to reestablish or improve patency of an occluded lumen. The endoprosthesis 4 may be secured by the physician to the dilation balloon 3 and catheter body 2. Preferably the manufacturer provides a preassembled unit with the distal end of the endoprosthesis prepositioned over the balloon at the distal end of the catheter. The device 1 is inserted into the femoral vein in the groin area and under fluoroscopic observation guided into the small saphenous vein 5 in the lower leg calf region.

[0018] Referring now to Figs. 5-8, small saphenous vein 5 is occluded with plaque deposits 7 on vein wall 6. The device 1 is maneuvered along small saphenous vein 5 to position the distal end of endoprosthesis 4 at the distal end of the treatment site, as shown in Fig. 5. The dilation balloon 3 is then inflated to radially expand, permanently deform, and position the distal end of endoprosthesis 4, thereby outwardly, radially compressing plaque deposits 7, as shown in Fig. 6. The dilation bal-

loon 3 is then deflated by the physician and dilation balloon 3 and catheter 2 are then moved proximally within endoprosthesis 4 slightly less than one balloon length to position L and inflated again, as shown in Fig. 7. This procedure is repeated until endoprosthesis 4 is radially expanded throughout its length and securely positioned, as shown in Fig. 8. After the entire length of endoprosthesis 4 is positioned, the dilation balloon 3 is deflated its final time and the catheter body 2 and dilation balloon 3 are removed from the patient. This preferred embodiment is particularly advantageous in that the open-knit design of the endoprosthesis 4 conforms to tortuous and contoured lumen walls without blocking side branches 8 and provides cross-sectional elasticity and high resistance to deformation. For further information concerning knitted stents in general see Strecker U.S. 4,922,905.

[0019] Referring now to Fig. 9, endoprosthesis 9 has an initial unexpanded length L_I of slightly smaller diameter than the diameter of the unexpanded remaining length L_R to secure endoprosthesis 9 on catheter body 2 over the standard length dilation balloon 3.

Alternative Embodiments

[0020] In another embodiment the balloon is fully deflated during placement and the stent in unexpanded form is secured to the catheter by overlapping resilient tubular members at the ends of the stent, constructed to release the distal end of the stent upon the first stage of inflation of the balloon, at the distal end, upon the first expansion of the stent, and to release the proximal end by the first step of axial movement of the catheter relative to the stent. Similar overlapping members are described in U.S. Patent 4,950,227 assigned to Boston Scientific Corporation.

[0021] In another embodiment, endoprosthesis 4 may be of a partially or totally self-expanding type. The dilation balloon 3 is then used to supplement the self-expansive forces of the endoprosthesis to assure full permanent expansion and secure positioning, rather than to provide the sole expansive force to position the endoprosthesis, as in the first preferred embodiment.

[0022] The knitted structure of the preferred embodiments mentioned above has attributes important to the realization of the full benefits of the invention, some of which have been mentioned above, especially the adaptability to long tortuous vessels, the ability to secure definite placement without change in length of the endoprosthesis or stent during placement, and the compliance with movement of the body, without dislodgement.

[0023] Nevertheless, in addition to the preferred tube-like knitted structure, the endoprosthesis 4 may also be made by crocheting, weaving, knotting, or forming by other means, and by other filament material. The endoprosthesis 4 adapted for vascular use may range for instance from 2-15 mm in diameter and 10-30 cm in length.

Claims

1. A medical device (1) comprising
a catheter (2) having a radially expandable portion;
a tubular shaped, elongate endoprosthesis (4) mounted on the catheter (2), the axial length of the radially expandable portion of the catheter (2) being less than the axial length of the endoprosthesis (4);
the endoprosthesis (4) is capable of radial expansion progressively in the axial direction, by means of the radially expandable portion of the catheter (2);
the radially expandable portion of the catheter is disposed within the portion of the endoprosthesis that is to be first expanded; **characterised in that**
the endoprosthesis comprises a filament material extending throughout the length of the endoprosthesis, the filament material being interconnected at a multiplicity of points along the length.

2. The medical device (1) of claim 1, wherein the endoprosthesis (4) includes an unexpanded first portion having a first diameter, and an unexpanded second portion having a second diameter larger than the first diameter, and the first portion is mounted on the catheter (2).

3. The medical device (1) of claim 2, the second diameter is larger than the diameter of the expandable portion in an unexpanded state.

4. The medical device (1) of claim 1, wherein the endoprosthesis (4) includes a first portion mounted on the catheter (2), the first portion being expandable without other unexpanded portions of the endoprosthesis (4) expanding.

5. The medical device (1) of any of claims 1 to 4, wherein the radially expandable portion of the catheter is an inflatable balloon (3).

6. The medical device (1) of any of claims 1 to 5, wherein the endoprosthesis (4) comprises a filament material.

7. The medical device (1) of claim 6, wherein the filament material forms interlocking loops.

8. The medical device (1) of claim 6, wherein the filament material is knitted.

9. The medical device (1) of any of claims 1 to 8, wherein the endoprosthesis (4) comprises a vascular stent.

10. The medical device (1) of claim 9, wherein the vascular stent is a self expandable stent.

11. The medical device (1) of claim 9, wherein the vascular stent is a balloon-expandable stent.

12. The medical device (1) of any of claims 1 to 11, wherein the endoprosthesis (4) is a knitted stent.

13. The medical device (1) of any of claims 1 to 12, wherein the endoprosthesis (4) is 10 to 30cm long.

14. The medical device (1) of any of claim 1 to 13, wherein the endoprosthesis (4) has a diameter of 2 to 15 mm.

15. The medical device (1) of any of claims 1 to 14, further comprising an overlapping resilient member mounted over the endoprosthesis (4).

Patentansprüche

1. Medizinische Vorrichtung (1) aufweisend einen Katheter (2) mit einem radial aufweitbaren Abschnitt;
eine rohrförmige längliche Endoprothese (4), die auf dem Katheter (2) montiert ist, wobei die axiale Länge des radial aufweitbaren Abschnitts des Katheters (2) kleiner als die axiale Länge der Endoprothese (4) ist;
wobei die Endoprothese (4) in der Lage ist, sich progressiv in der Axialrichtung mittels des radial aufweitbaren Abschnitts des Katheters (2) radial aufzuweiten;
wobei der radial aufweitbare Abschnitt des Katheters in dem Abschnitt der Endoprothese angeordnet ist, welcher sich als erstes aufweitet;
dadurch gekennzeichnet, dass die Endoprothese ein Fasermaterial aufweist, welches sich über die Länge der Endoprothese erstreckt, wobei das Fasermaterial in einer Vielzahl von Punkten entlang der Länge untereinander verbunden ist.

2. Medizinische Vorrichtung (1) nach Anspruch 1, bei welcher die Endoprothese (4) einen nicht-aufgeweiteten ersten Abschnitt mit einem ersten Durchmesser und einen nicht-aufgeweiteten zweiten Abschnitt mit einem zweiten Durchmesser, welcher größer als der erste Durchmesser ist, aufweist und bei welcher der erste Abschnitt auf dem Katheter (2) montiert ist.

3. Medizinische Vorrichtung (1) nach Anspruch 2, bei welcher der zweite Durchmesser größer als der Durchmesser des aufweitbaren Abschnitts in einem nicht-aufgeweiteten Zustand ist.

4. Medizinische Vorrichtung (1) nach Anspruch 1, bei welcher die Endoprothese (4) einen ersten Abschnitt umfasst, der auf dem Katheter (2) montiert ist, wobei der erste Abschnitt aufweitbar ist, ohne dass andere nicht-aufgeweitete Abschnitte der Endoprothese (4) sich aufweiten.

5. Medizinische Vorrichtung (1) nach einem der Ansprüche 1 bis 4, bei welcher der radial aufweitbare Abschnitt des Katheters ein aufblasbarer Ballon (3) ist.

6. Medizinische Vorrichtung (1) nach einem der Ansprüche 1 bis 5, bei welcher die Endoprothese (4) ein Fasermaterial aufweist.

7. Medizinische Vorrichtung (1) nach Anspruch 6, bei welcher das Fasermaterial ineinander greifende Schlingen ausbildet.

8. Medizinische Vorrichtung (1) nach Anspruch 6, bei welcher das Fasermaterial gestrickt/gewirkt ist.

9. Medizinische Vorrichtung (1) nach einem der Ansprüche 1 bis 8, bei welcher die Endoprothese (4) einen Gefäßstent aufweist.

10. Medizinische Vorrichtung (1) nach Anspruch 9, bei welcher der Gefäßstent ein selbstaufweitbarer Stent ist.

11. Medizinische Vorrichtung (1) nach Anspruch 9, bei welcher der Gefäßstent ein Ballon-aufweitbarer Stent ist.

12. Medizinische Vorrichtung (1) nach einem der Ansprüche 1 bis 11, bei welcher die Endoprothese (4) ein gestrickter/gewirkter Stent ist.

13. Medizinische Vorrichtung (1) nach einem der Ansprüche 1 bis 12, bei welcher die Endoprothese (4) 10 bis 30 cm lang ist.

14. Medizinische Vorrichtung (1) nach einem der Ansprüche 1 bis 13, bei welcher die Endoprothese (4) einen Durchmesser von 2 bis 15 mm aufweist.

15. Medizinische Vorrichtung (1) nach einem der Ansprüche 1 bis 14, weiter aufweisend ein überlappendes flexibles Element, welches über der Endoprothese (4) montiert ist.

Revendications

1. Un dispositif médical (1) comprenant :

un cathéter (2) ayant une partie apte à être dilatée radialement ;
une endoprothèse (4) allongée, de forme tubulaire, montée sur le cathéter (2), la longueur axiale de la partie apte à être dilatée radiale-

ment du cathéter (2) étant inférieure à la longueur axiale de l'endoprothèse (4) ;
l'endoprothèse (4) est capable d'une dilatation radiale progressivement dans la direction axiale au moyen de la partie apte à être dilatée radialement du cathéter (2) ;
la partie apte à être dilatée radialement du cathéter est disposée dans la partie de l'endoprothèse qui est tout d'abord dilatée, **caractérisé en ce que** :

l'endoprothèse comprend un matériau à filament s'étendant au travers de la longueur de l'endoprothèse, le matériau à filament étant interrelié à une pluralité de points sur la longueur.

2. Le dispositif médical (1) selon la revendication 1, dans lequel l'endoprothèse (4) comprend une première partie non dilatée ayant un premier diamètre et une deuxième partie non dilatée ayant un deuxième diamètre plus grand que le premier diamètre, et la première partie est montée sur le cathéter (2).

3. Le dispositif médical (1) selon la revendication 2, dans lequel le deuxième diamètre est supérieur au diamètre de la partie apte à être dilatée dans un état non dilaté.

4. Le dispositif médical (1) selon la revendication 1, dans lequel l'endoprothèse (4) comprend une première partie montée sur le cathéter (2), la première partie étant apte à être dilatée sans autres parties non dilatées de l'endoprothèse (4) se dilatant.

5. Le dispositif médical (1) selon l'une quelconque des revendications 1 à 4, dans lequel la partie apte à être dilatée radialement du cathéter est un ballon gonflable (3).

6. Le dispositif médical (1) selon l'une quelconque des revendications 1 à 5, dans lequel l'endoprothèse (4) comprend un matériau à filament.

7. Le dispositif médical (1) selon la revendication 6, dans lequel le matériau à filament forme des boucles s'inter-verrouillant.

8. Le dispositif médical (1) selon la revendication 6, dans lequel le matériau à filament est tricoté.

9. Le dispositif médical (1) selon l'une quelconque des revendications 1 à 8, dans lequel l'endoprothèse (4) comprend un extenseur vasculaire.

10. Le dispositif médical (1) selon la revendication 9, dans lequel l'extenseur vasculaire est un extenseur auto-dilatable.

11. Le dispositif médical (1) selon la revendication 9, dans lequel l'extenseur vasculaire est un extenseur dilatable à ballon.

12. Le dispositif médical (1) selon l'une quelconque des revendications 1 à 11, dans lequel l'endoprothèse (4) est un extenseur tricoté.

13. Le dispositif médical (1) selon l'une quelconque des revendications 1 à 12, dans lequel l'endoprothèse (4) présente une longueur de 10 à 30 cm.

14. Le dispositif médical (1) selon l'une quelconque des revendications 1 à 13, dans lequel l'endoprothèse (4) présente un diamètre de 2 à 15 mm.

15. Le dispositif médical (1) selon l'une quelconque des revendications 1 à 14, comprenant, en outre, un élément résilient de recouvrement monté sur l'endoprothèse (4).

FIG. 1

FIG. 1a

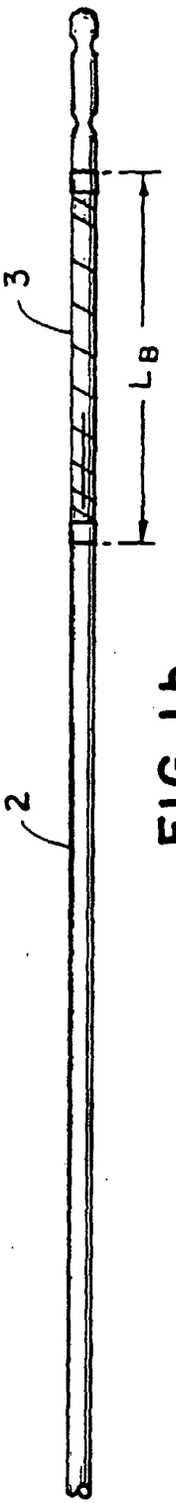

FIG. 1b

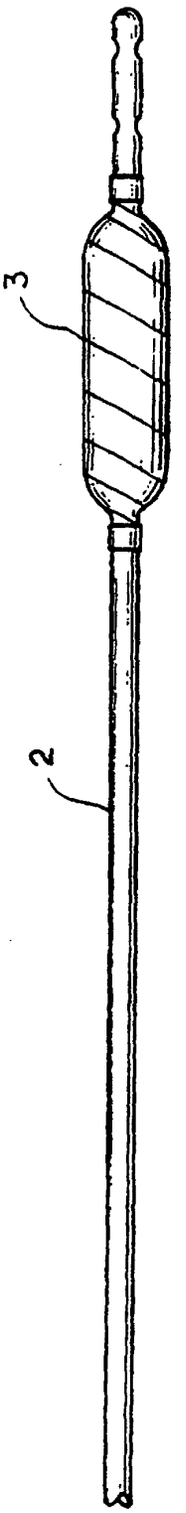

FIG. 1c

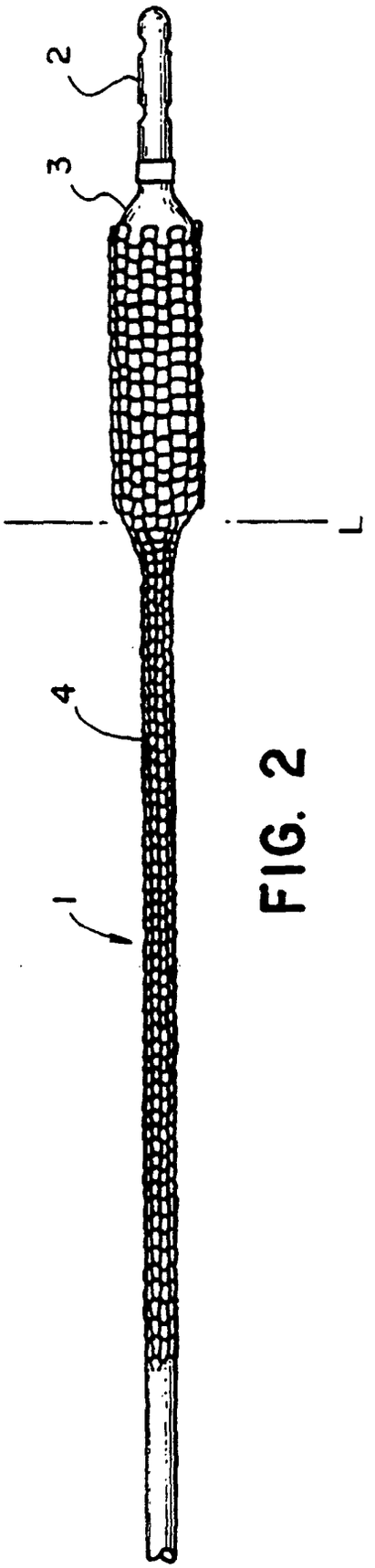

FIG. 2

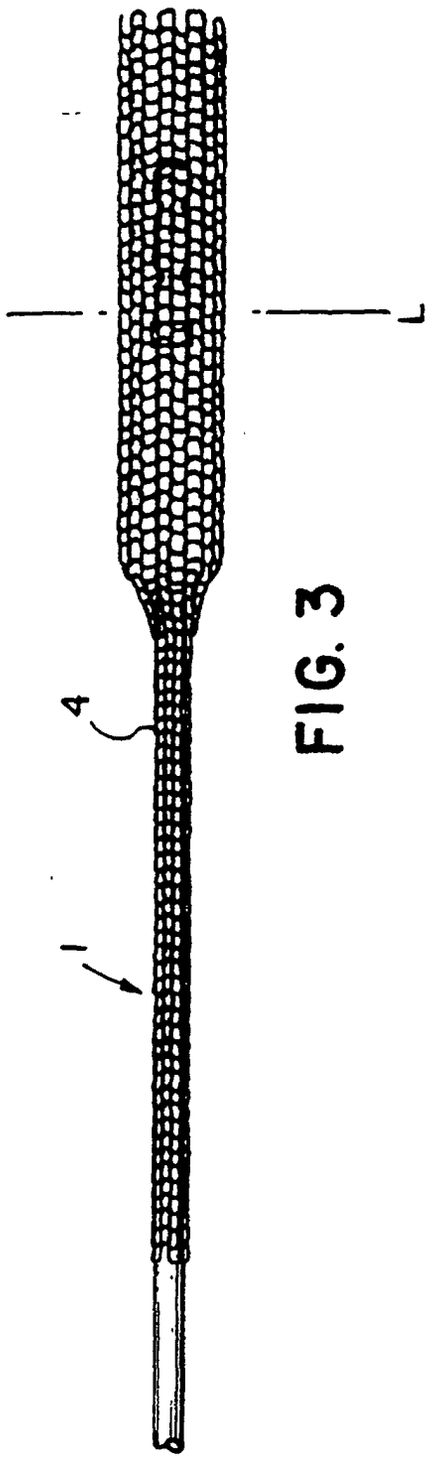

FIG. 3

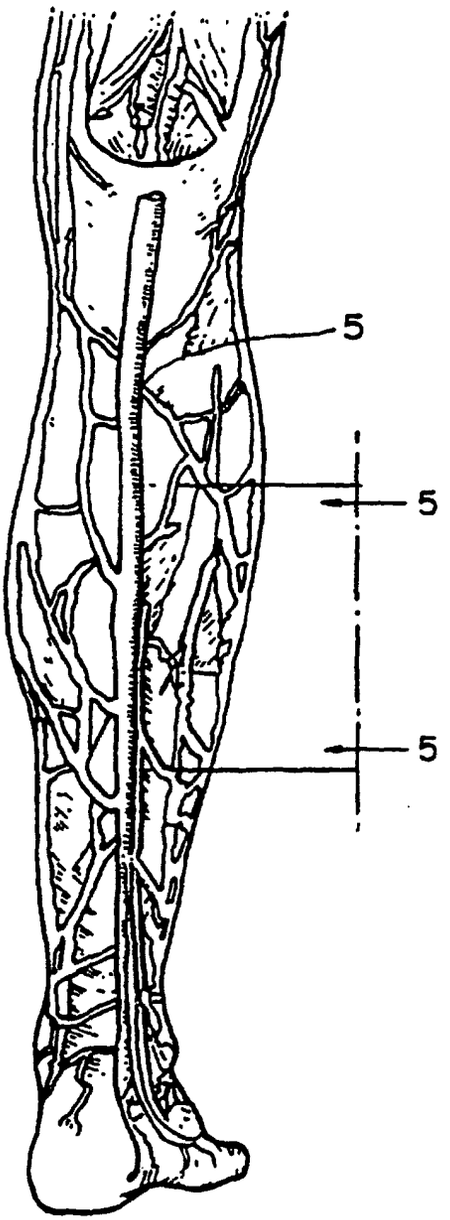

FIG. 4

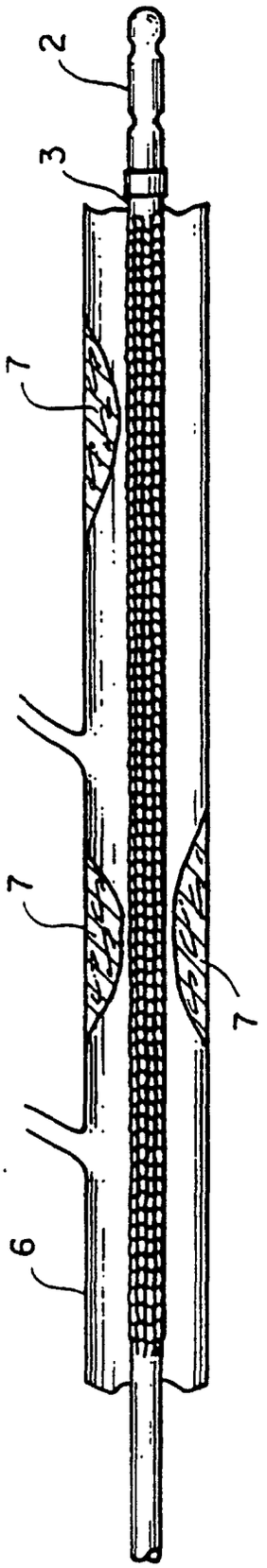

FIG. 5

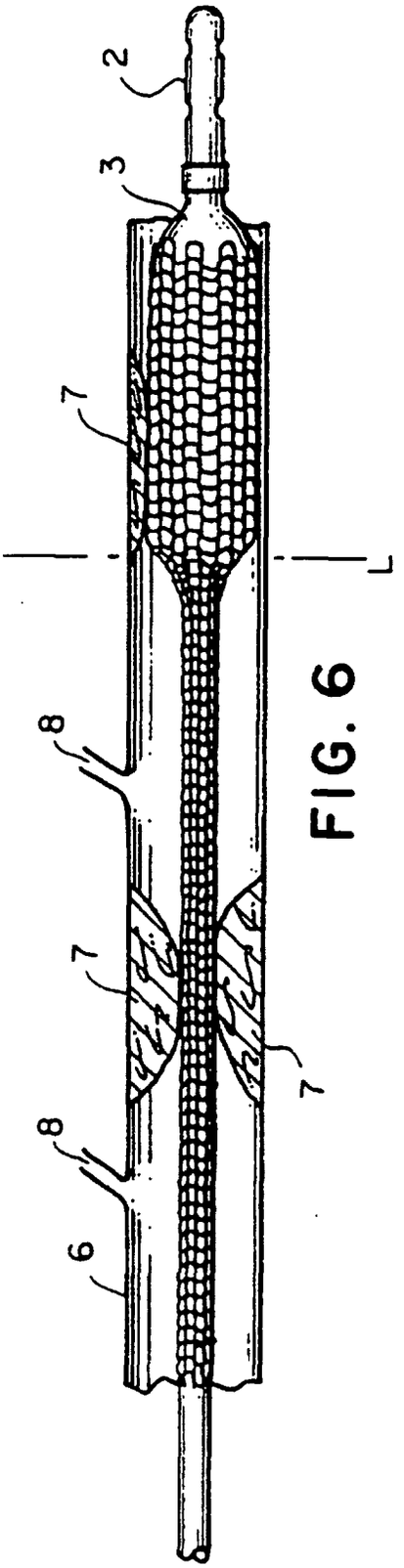

FIG. 6

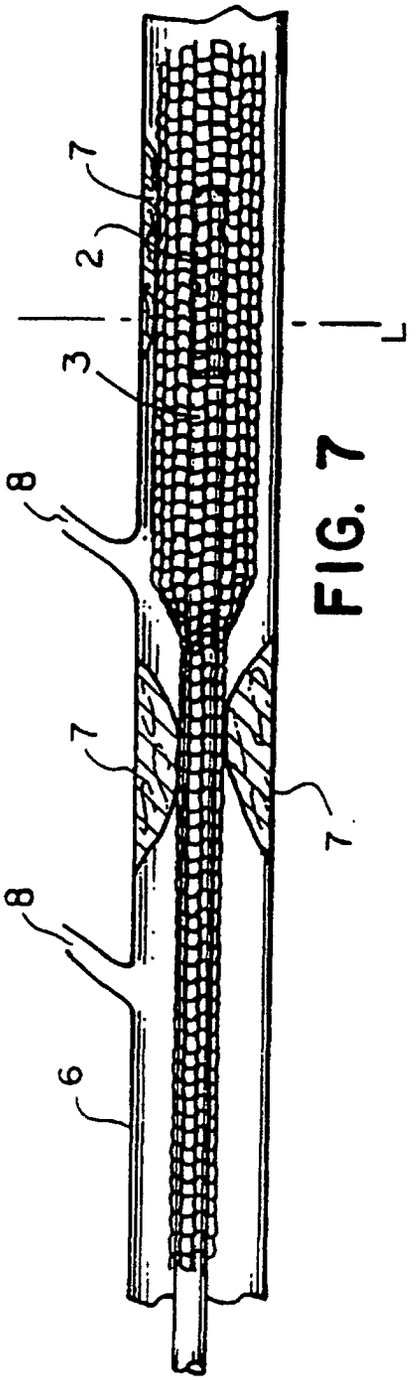

FIG. 7

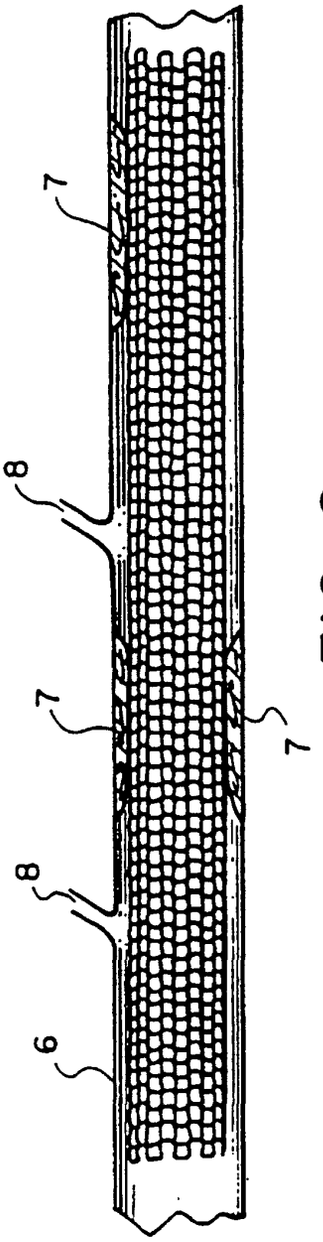

FIG. 8

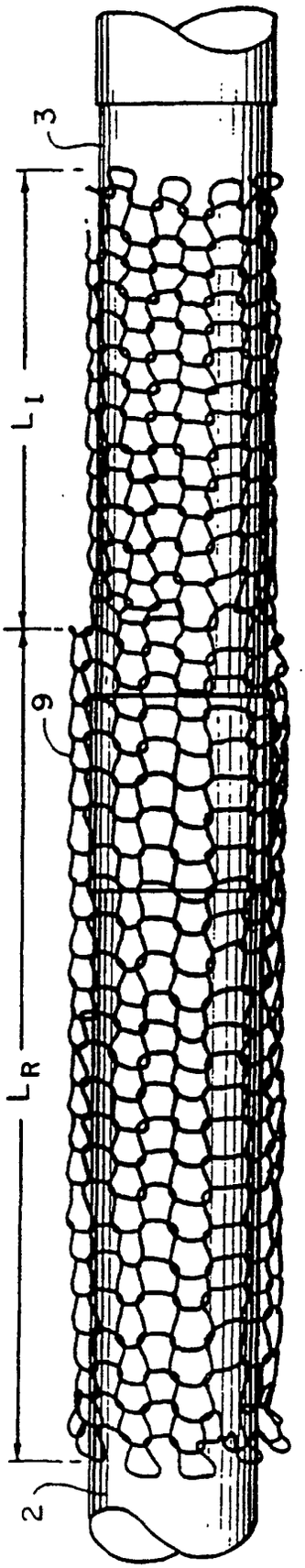

FIG. 9